

## **REMARKS**

### **A. 35 U.S.C. § 102**

In the Office Action of October 20, 2004, claims 1-6, 8, 14, 15 and 21-26 were stand rejected under 35 U.S.C. §102(b) as being anticipated by Soloviev et al. Independent claim 1, as amended, recites “a separator having a structure to at least partially separate said portion of said epithelial material from said cornea.” The Office Action has asserted that Soloviev et al.’s hold plates 8 are separators. However, the bottom edges of the hold plates 8 have a curved structure so that the bottom edges rest on portions of the cornea that have the same curvature (FIG. 5, Col. 2. l. 67 – Col. 3. l. 2). There is no suggestion in Soloviev et al. that the hold plates 8 have a structure to separate a portion of an epithelial material in the manner recited in claim 1. Accordingly, claim 1 is not anticipated by Soloviev et al.

Soloviev et al. does not anticipate claim 1 for the additional reason that it lacks a rotating drum “positioned relative to said separator so as to receive said separated portion of said epithelial material from said separator.” The Office Action has asserted that drum 11 anticipates the recited drum. However, the cutaway view of FIG. 2 shows that the drum 11 is positioned so that it cannot receive a separated epithelial material from the hold plates 8. In particular, the drum 11 appears to be positioned above the hold plates 8 and held within a groove formed in the body 1. Thus, the drum 11 is prevented from receiving any material from the hold plates 8. Accordingly, claim 1 is not anticipated by Soloviev et al.

Claim 2 is not anticipated by Soloviev et al. because it previously recited dimensions of the internal and external diameters of the seating and now recites dimensions of the internal diameter. The Office Action asserts that ring 4 corresponds to the recited seating. However, Soloviev fails to provide any dimensions for the ring 4. The Office Action states “that the procedure in figures 2 and 5 are capable of having the ring with the internal diameter ranging from about 10-12 mm and with the external diameter from about 13-16mm” (emphasis

added). The standard for anticipation is that the reference explicitly or inherently discloses each element in the claim. Having an embodiment capable of having a claimed feature is not anticipation. Accordingly, the rejections of claim 2 and its dependent claims 3-6, 8, 14, 15 and 24 are improper and should be withdrawn.

Claim 14 is not anticipated by Soloviev et al. because it previously recited a separator support that freely slid in a groove and now recites the support moveable along a track. The Office Action has failed to identify a separator support in Soloviev et al. that anticipates the recited separator support. Accordingly, the rejection of claim 14 is improper and should be withdrawn.

Claims 15 and 25 are not anticipated by Soloviev et al. because they recite either a movement device (claim 15) or an oscillation device (claim 25) coupled to either a separator support (claim 15) or a separator (claim 25). The Office Action has failed to identify a device in Soloviev et al. that anticipates the recited movement/oscillation device. Accordingly, the rejections of claims 15 and 25 are improper and should be withdrawn.

Claim 22 is not anticipated by Soloviev et al. because it recites a drum that includes a hole. While the Office Action has asserted that drum 11 corresponds to the recited drum, the Office Action has failed to identify where Soloviev et al. discloses having a hole formed in drum 11. Accordingly, the rejections of claim 22 and its dependent claim 23 are improper and should be withdrawn.

Claim 24 is not anticipated by Soloviev et al. because it previously recited a separator support that fits in a groove and now recites the support slidably engages a track of the seating. The Office Action has failed to identify a separator support in Soloviev et al. that anticipates the recited separator support. Accordingly, the rejections of claim 24 and its dependent claim 6 are improper and should be withdrawn.

For at least the reasons given above, the rejections are either improper or overcome and so should be withdrawn.

Note that claim 1 has been amended to broaden the scope and/or clarify the scope of the material being separated and so such amendments are not

related to patentability as defined in *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) (*en banc*), *overruled in part*, 535 U.S. 722 (2002) (hereinafter *Festo I*).

Claim 2 has been amended to stylize the “wherein” clause, delete reference to a ring and to replace certain references to a “ring” to a “seating.” Since the stylized amendments clarify the invention and do not change the intended meaning or scope of the claim, such amendments are not related to patentability as defined in *Festo I*. Since the amendments regarding “ring” and “seating” broaden and/or clarify the invention, the amendments are not related to patentability as defined in *Festo I*.

Claims 3 and 4 have been amended to replace “excise” with “incise” which is broader in meaning and so the amendments are not related to patentability as defined in *Festo I*.

Claim 8 has been amended to replace certain references to a “ring” to a “seating.” Since the amendments broaden and/or clarify the invention, the amendments are not related to patentability as defined in *Festo I*.

Claims 22 and 23 have been amended to replace “the” with “said.” Since the amendments regard matters of style and do not change the intended meaning or scope of the claims, such amendments are not related to patentability as defined in *Festo I*.

Claims 24 and 25 have been amended to replace “the separator” with “said separator.” Since the amendments regard matters of style and do not change the intended meaning or scope of the claims, such amendments are not related to patentability as defined in *Festo I*.

Claim 26 has been amended to delete reference to a ring and to replace certain references to a “ring” to a “seating.” Since the amendments regarding “ring” and “seating” broaden and/or clarify the invention, the amendments are not related to patentability as defined in *Festo I*.

**B. Rejections under 35 U.S.C. § 103**

**1. Soloviev et al. and Bair et al.**

Claims 9-12 were rejected under 35 U.S.C. §103(a) as being obvious in view of Soloviev et al. and Bair et al. Applicants respectfully traverse the rejection for several reasons. First, claim 12 has been canceled rendering its rejection moot. Second, Soloviev et al. is directed to non-analogous art and so cannot be combined with Bair et al.

The two-fold test for non-analogous art is as follows:

A reference is analogous if it is from the same field of endeavor as the invention. Similarity in the structure and function of the invention and the prior art is indicative that the prior art is within the inventor's field of endeavor. If a reference is outside the inventor's field of endeavor, it is still analogous art if the reference is reasonably pertinent to the particular problem with which the inventor is involved. *State Contracting & Engineering Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1489 (Fed. Cir. 2003); *In re Clay*, 966 F.2d 656, 658-59, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992).

Upon applying the first part of the test, it is apparent that Soloviev et al. is not within Applicants' field of endeavor. Applicants' claimed invention is in the field of devices that separate an epithelial material from a cornea. In contrast, Soloviev et al. is directed to the field of devices "for marking out the cornea in ophthalmosurgery" so that accurate incisions in the eye can be made (Col. 1, ll. 6-8 and Col. 3, ll. 35-37). Nowhere does Soloviev et al. discuss removing an epithelial material.

Besides not being within Applicants' field of endeavor, Soloviev et al. is not reasonably pertinent to the particular problem with which the Applicants are involved. As stated at page 1 of Applicants' specification, one of the problems attempted to be solved is that prior LASEK processes used alcohol to devitalize an epithelial material which can lead to severe epithelial cell loss that can make the epithelial material unusable as a protective agent. (Page 3, lines 15-24).

Upon reviewing Soloviev et al., it is apparent that Soloviev et al. does not address Applicants' problem. In particular, Soloviev et al. is directed to solving the problem of prior non-perforating incisions in the cornea failing to provide pinpoint accuracy (Col. 1, ll. 15-35). Since Soloviev et al. is not reasonably pertinent to Applicants' particular problem, Soloviev et al. fails the second part of the test. Accordingly, it is respectfully submitted that a person having ordinary skill in the art of epithelial material removing devices would not, without other suggestion, turn to the completely non-analogous art of cornea marking devices to find answers for improving the removal of an epithelial material.

Even if Soloviev et al. is considered to be analogous art, the rejection is improper because there is no motivation in either Soloviev et al. or Bair et al. to oscillate the hold plates 8 of Soloviev et al. at a frequency ranging from about 10Hz to about 10KHz as recited in claim 9. The hold plates 8 are designed to remain stationary at a position on the cornea during marking. If the hold plates 8 oscillated at the claimed frequency range while moving to the desired marking position, they could damage the cornea. If the hold plates 8 oscillated at the desired marking position, then it would not be possible to obtain an accurate mark on the cornea. Since oscillation of the hold plates 8 would damage and/or lead to inaccurate marking, Soloviev et al. teaches away from oscillating hold plates 8 and so the rejection of claim 9 and its dependent claims 10-12 is improper and should be withdrawn.

The rejections of claims 10 and 11 are improper for the additional reason that neither Soloviev et al. nor Bair et al. disclose or suggest oscillating a separator via electromagnetic forces (claim 10) or piezoelectric forces (claim 11). It is noted that the rejection on page 4 of the Office Action based on the combination of Soloviev et al., Bair et al. and Tanne concedes this point.

On a related issue, Applicants note that the rejection briefly makes reference to the Amano reference. It is believed that this reference was in error and was intended to be directed to Soloviev et al. The response above has made this assumption.

Note that claim 9 has been amended to be in independent form, to the extent that such amendments incorporate subject matter that was inherently present in the previous version of the claim, such amendments are not related to patentability. See, *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002) (hereinafter *Festo II*). To the extent that the claim has been amended to broaden the scope and/or clarify the scope of the material being separated, such amendments are not related to patentability as defined in *Festo I*.

Claims 10 and 11 have been amended to stylize the language in that “the separator” has been changed to “said separator” and “oscillation is provided by” has been replaced by “oscillates via.” Since the amendments clarify the invention and do not change the intended meaning or scope of the claim, such amendments are not related to patentability as defined in *Festo I*.

## **2. Soloviev et al., Bair et al. and Tanne**

Claims 10-12 were rejected under 35 U.S.C. §103(a) as being obvious in view of Soloviev et al., Bair et al. and Tanne. Applicants respectfully traverse the rejection for several reasons. First, claim 12 has been canceled rendering its rejection moot. Second, Tanne is directed to non-analogous art and so cannot be combined with Soloviev et al. and Bair et al. Tanne is not within Applicants’ field of devices that separate an epithelial material from a cornea. In contrast, Tanne is directed to the field of devices for automatically cutting into the cornea to perform radial keratotomy procedure (Col. 7, ll. 19-58). Nowhere does Tanne discuss removing an epithelial material.

Besides not being within Applicants’ field of endeavor, Tanne is not reasonably pertinent to the particular problem with which the Applicants are involved. As stated previously in Section B.1, one of the problems attempted to be solved by the Applicants is that prior LASEK processes used alcohol to devitalize an epithelial material which can lead to severe epithelial cell loss that can make the epithelial material unusable as a protective agent.

Tanne does not address Applicants' problem. In particular, Tanne is directed to solving the problem of predictable and consistent cutting of a cornea. (Col. 1, l. 31 – Col. 3, l. 3). Since Tanne is not reasonably pertinent to Applicants' particular problem, Tanne is directed to non-analogous art and so the rejection is improper.

Even if Tanne is considered to be analogous art, the rejection is improper because there is no motivation in Tanne to oscillate the hold plates 8 of Soloviev et al. at a frequency ranging from about 10Hz to about 10KHz as recited in claim 9 from which claims 10-11 depend. As mentioned in Section B.1, oscillating the hold plates 8 of Soloviev et al. would damage and/or lead to inaccurate marking and so Soloviev et al. teaches away from oscillating hold plates 8 and so the rejection of claims 10 and 11 is improper and should be withdrawn.

The rejections of claims 10 and 11 are improper for the additional reason that Tanne does not disclose or suggest oscillating a separator via electromagnetic forces (claim 10) or piezoelectric forces (claim 11). Indeed, Tanne does not appear to disclose oscillating its knife 110 at all. It is noted that the passage relied on by the Office Action mentions linear motion (Col. 5, l. 38) but not oscillating motion.

### **3. Soloviev et al. and Ruiz et al.**

Claim 13 was rejected under 35 U.S.C. §103(a) as being obvious in view of Soloviev et al. and Ruiz et al. Applicants respectfully traverse the rejection. The rejection is improper because there is no motivation in Ruiz et al. to use an oscillating device that acts on the hold plates 8 of Soloviev et al. As mentioned in Section B.1, oscillating the hold plates 8 of Soloviev et al. would damage and/or lead to inaccurate marking and so Soloviev et al. teaches away from oscillating hold plates 8 and so the rejection of claims 13 is improper and should be withdrawn.

Claim 13 has been amended to stylize the language in that "the separator" has been changed to "said separator" and "the rotating" has been changed to "said rotating." Since the amendments clarify the invention and do not change

the intended meaning or scope of the claim, such amendments are not related to patentability as defined in *Festo I*.

Claim 13 has been also amended to broaden its coverage by replacing “gears” with “member”, replacing “toothed rails” with “a track” and deleting mention of the orientation relative to a groove. Since the amendments broaden the scope of the claim, they do not fall under the purview of *Festo I or II*.

**4. Soloviev et al.**

Claim 17 was rejected under 35 U.S.C. §103(a) as being obvious in view of Soloviev et al. Applicants respectfully traverse the rejection for several reasons. First, Soloviev et al. is directed to non-analogous art as pointed out in Section B.1. Second, claim 17 depends from independent claim 1 which recites “a separator having a structure to at least partially separate said portion of said epithelial material from said cornea.” As pointed out in Section A, there is no suggestion in Soloviev et al. to alter its hold plates 8 to have a structure to separate an epithelial material. Accordingly, claim 17 is not rendered obvious by Soloviev et al.

The rejection should be withdrawn for the additional reason that Soloviev et al. does not suggest using a rotating drum “positioned relative to said separator so as to receive said separated portion of said epithelial layer from said separator” as recited in claim 1. As pointed out in Section A, Soloviev et al.’s drum 11 is positioned so that it cannot receive a separated epithelial material from the hold plates 8. This teaching away shows that claim 17 is not rendered obvious by Soloviev et al.

**5. Soloviev et al. and Tomiyama et al.**

Claims 18-20 were rejected under 35 U.S.C. §103(a) as being obvious in view of Soloviev et al. and Tomiyama et al. Applicants respectfully traverse the rejection for several reasons. First, Soloviev et al. is directed to non-analogous art as pointed out in Section B.1. Similarly, Tomiyama et al. is directed to non-analogous art. Tomiyama et al. is not within Applicants’ field of devices that separate an epithelial material from a cornea. In contrast, Tomiyama et al. is



directed to the field of developers for developing an electrostatic image (Col. 1, ll. 14-18). Nowhere does Tomiyama et al. discuss removing an epithelial material.

Besides not being within Applicants' field of endeavor, Tomiyama et al. is not reasonably pertinent to the particular problem with which the Applicants are involved. As stated previously in Section B.1, one of the problems attempted to be solved by the Applicants is that prior LASEK processes used alcohol to devitalize an epithelial material which can lead to severe epithelial cell loss that can make the epithelial material unusable as a protective agent.

Tomiyama et al. does not address Applicants' problem. In particular, Tomiyama et al. is directed to solving the problems of 1) developers of electrostatic images that tend to cause the melt adhesion of toner to a photosensitive member (Col. 5, ll. 38-41) and 2) developers that cause charge non-uniformity during the formation of electrostatic images (Col. 5, ll. 42-47). Since Tomiyama et al. is not reasonably pertinent to Applicants' particular problem, Tomiyama et al. is directed to non-analogous art and so the rejection is improper.

Even if Tomiyama et al. is considered to be analogous art, the rejection is improper because there is no motivation in Tomiyama et al. to alter Soloviev et al.'s hold plates 8 to have a structure to separate an epithelial material. Furthermore, Tomiyama et al. does not suggest altering Soloviev et al.'s drum 11 to be "positioned relative to said separator so as to receive said separated portion of said epithelial material from said separator." As pointed out in Section A, Soloviev et al.'s drum 11 is positioned so that it cannot receive a separated epithelial material from the hold plates 8. This teaching away shows that claim 17 is not rendered obvious by Soloviev et al.

Claim 18 has been amended so as to broaden its coverage and so its amendment is not related to patentability as defined in *Festo I*.

Claims 19-20 have been amended to stylize the language in that "the" has been changed to "said" in several instances. Since the amendments clarify the

invention and do not change the intended meaning or scope of the claim, such amendments are not related to patentability as defined in *Festo I.*

**C. Claims 27-42**

New claims 27-42 depend directly or indirectly on claim 1 and so are patentable over Soloviev et al. for at least the same reasons given above in Section A with respect to claim 1.

Note that claims 27-42 are being presented to provide additional protection for the device of claim 1 and so are not being presented for reasons of patentability as defined in *Festo I.*

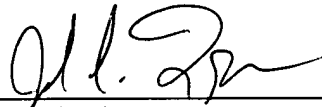
**D. Claims 43-64**

Claims 43-64 are being presented to provide patent protection for various devices and so are not being presented for reasons of patentability as defined in *Festo I.*

**CONCLUSION**

In view of the arguments above, Applicants respectfully submit that all of the pending claims 1-6, 8-11, 13-15 and 17-64 are in condition for allowance and seeks an early allowance thereof. If for any reason, the Examiner is unable to allow the application in the next Office Action and believes that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorneys at (312) 321-4200.

Respectfully submitted,



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John C. Freeman  
Registration No. 34,483  
Attorney for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
(312) 321-4200